



Neurocrine Biosciences Announces Positive Results From Second Phase II Study With Its Orally Active GnRH Receptor Antagonist in Endometriosis

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SAN DIEGO, Jan. 8 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced positive preliminary results from its second 'proof of concept', safety and efficacy Phase II clinical trial over a 3-month treatment period using its proprietary, orally-active nonpeptide Gonadotropin-Releasing Hormone (GnRH) receptor antagonist (NBI-56418) in patients with endometriosis. In 2006, the Company previously reported positive results from the completion of the first 3-month 'proof of concept' double-blind treatment period and additional 3-month follow up period of a parallel Phase II exploratory trial with NBI-56418 given once daily to endometriosis patients. This second exploratory study, which was also started in 2006, was designed to evaluate dose-response and twice daily dosing.

The newly reported preliminary 3-month data comes from a multi-center, randomized, double-blind, placebo-controlled trial involving patients with a confirmed diagnosis of endometriosis. The study followed a parallel-group design in which 68 subjects were randomized to one of three treatment groups: placebo, 50 mg of NBI-56418, or 100 mg of NBI-56418 each administered twice daily. Dosing started on Day 2 to Day 7 of the menstrual cycle and continued over 12 weeks with assessments of symptoms and signs of disease conducted at 4-week intervals using the Composite Pelvic Sign and Symptoms Score (CPSSS) for the primary endpoint of reduction in endometriosis symptoms. In addition, assessment of pain intensity was measured daily by a Visual Analog Scale (VAS) and collected by electronic diary. Full data regarding treatment impact on menses and a variety of biomarkers will be available at the completion of the ongoing 3-month safety follow-up period.

For the primary endpoint of CPSSS, which has a maximum possible value of 15, mean values at baseline were 7.8, 7.2 and 8.3 for the placebo, 50 mg and 100 mg groups respectively. After treatment, there were reductions of 4.3 (placebo), 4.7 (50 mg) and 5.3 (100 mg) points in the score at week 12. The dysmenorrhea component of the scale showed the most consistent dose-related reductions of 0.9, 1.3 and 1.9 points and dysmenorrhea was absent at 12 weeks in 81% of women randomized to the 100 mg group compared to 17% of the placebo recipients. The VAS data reveal dose-related improvements in "worst pain" (maximum score), particularly at Week 4 with reductions of 3 (placebo), 17 (50 mg) and 20 (100 mg) from the screening period maximum VAS means of 73, 68 and 72 respectively.

The study drug was generally well tolerated and rates of treatment-emergent adverse events were similar across treatment groups. The incidence of hot flashes reported by the NBI-56418 treated groups were comparable to that reported by the placebo group. Mean estradiol levels at Week 12 were 89 pg/ml, 44 pg/ml and 25 pg/ml in the placebo, 50 mg and 100 mg groups respectively. Plasma n-telopeptide, an important biomarker in assessing risk of bone loss, showed values that remained in the normal range and most subjects had no significant change in n-telopeptide. There were no trends of treatment related changes in ECG or standard clinical laboratory assessments.

"The results of the second exploratory Phase II study are consistent with the first study reported in 2006. Our GnRH antagonist demonstrated dose-related reductions of estradiol without evidence of increased risk of bone loss. The reductions in pain scores were reported within days of treatment initiation for some women and patients with initial improvement continued to benefit throughout the treatment period. The extent of estradiol suppression and lack of undesirable metabolic consequences suggest that even higher doses may be acceptable with the potential for greater symptom reduction," said Chris O'Brien, M.D., Senior Vice President of Clinical Development and Chief Medical Officer for Neurocrine Biosciences.

"Based on the combined data of the two parallel 'proof of concept' Phase II clinical trials with NBI-56418, we have initiated an expanded 6-month study in several hundred patients with endometriosis, which will assess the impact of treatment on bone mineral density as well as on endometriosis symptoms. The 6-month study was initiated in the 4th Quarter of 2006," added Dr. O'Brien.

Study Design for the Six-Month Phase II Clinical Study with GnRH for Endometriosis -Now Enrolling Patients

Neurocrine initiated the Phase IIb study in the 4th quarter of 2006 in which 240 patients with endometriosis will be treated over a 6-month treatment period. This multi-center, randomized, double-blind, study includes three treatment groups, with two doses of NBI-56418, 150 mg once a day and 75 mg twice daily, and an active comparator. In addition to confirming the effect of NBI-56418 on endometriosis symptoms, this study is designed primarily to assess the impact of longer treatment on bone mineral density as measured by DEXA scan at the conclusion of dosing and at 6-months and 12-months post-treatment. The 6-month results, together with data from the previous two Phase II studies will be the basis for securing agreement to a registration plan acceptable to the FDA.

Additional Program Developments

Finally, the Company has also conducted a Phase I study in male volunteers as part of the Benign Prostate Hyperplasia (BPH) development program. Preliminary results demonstrate that NBI-56418, dosed once or twice daily over a two-week period, produced a dose-related reduction of testosterone. In addition, the study drug was safe and well tolerated. These results will be used for the selection of dosing and dosing regimen for future studies, which are currently under evaluation.

Background

Approximately 6 million women in the US have endometriosis, many with severe or moderate symptoms according to The Mattson Jack Group. Many patients are believed to be misdiagnosed or undiagnosed. The impact of endometriosis on the lives of sufferers can be significant -- adversely affecting the ability of patients to maintain relationships and employment.

Surgery and medical treatments are currently available for women with endometriosis. Surgery is not acceptable to many patients. Although indicated for endometriosis, medical therapies, such as the injectable GnRH agonist leuprolide or injectable progesterone, are associated with a range of potentially unacceptable side effects, including bone loss and hot flashes. Consequently, prescribing physicians often reserve these medical interventions for patients with severe endometriosis. For the majority of endometriosis patients suffering from moderate or mild symptoms, the remaining treatment options, oral contraceptives and analgesics, are only partially effective.

Neurocrine Biosciences, Inc. is a product-based biopharmaceutical Company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including insomnia, anxiety, depression, endometriosis, pain, irritable bowel syndrome, and autoimmunity. Neurocrine Biosciences, Inc. news releases are available through the Company's website via the Internet at <http://www.neurocrine.com>

In addition to historical facts, this press release may contain forward- looking statements that involve a number of risks and uncertainties. Among the factors that could cause actual results to differ materially from those indicated in the forward looking statements are risks and uncertainties associated with Neurocrine's business and finances in general including the risks and uncertainties associated with, or arising out of, drug discovery, pre-clinical and clinical development of pharmaceutical products. Specifically, the Company faces risks and uncertainties arising out of its GnRH clinical development program including risk that its lead candidate, NBI- 56418, will not proceed to later stage clinical trials; risk that should NBI- 56418 may prove unsuitable for continued development, the Company will not be successful in identifying alternative GnRH antagonist products that are safe and effective; risk relating to the Company's dependence on contract manufacturers for GnRH antagonist product clinical drug supply and compliance with regulatory requirements for marketing approval; risks that the Company may be dependent on corporate collaborators for commercial manufacturing and marketing and sales activities for its GnRH antagonist products; uncertainties relating to patent protection for the Company's GnRH antagonist products and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's GnRH antagonist products; risk that the Company will be unable to raise additional funding required to complete development of its GnRH antagonist product candidates; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2005 and report on Form 10-Q for the quarter ended September 30, 2006. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

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